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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,920	02/20/2002	Motasim Sirhan	020460-000230US	1180

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,920	SIRHAN ET AL.	
	Examiner	Art Unit	
	Sarah K. Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,11-18,20-23,26-28,31,32,35,45-49,69,71,73,74,76,79-85,97-101, and 107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,11-18,20-23,26-28,31,32,35,45-49,69,71,73,74,76,79-85,97-101 and 107.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/2/06 has been entered.

Claim Objections

2. Claims 11,49, and 101 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1,2,11-18,20-23,26-28,31,32,35,45-49,69,71,73,74,76,79-85,97-101, and 107 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an axial groove on the balloon structure shaft, does not reasonably provide enablement for a groove on the balloon structure sleeve of the

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embodiment in Figure 5A. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. If there were a slit in the balloon, the device would be inoperable, because the balloon would not be inflatable. The disclosure does not support a balloon that does not extend a full circumference.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1,2,11-18,20-23,26-28,31,32,35,45-49,69,71,73,74,76,79-85,97-101, and 107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 2 include the sleeve passage as part of the balloon structure in line 4. The claims then require an axial groove along at least a portion of the structure and the passage. Since the passage is part of the structure, this limitation is contradictory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 1,2,11-18,20-23,26-28,31,32,35,45-49,69,71,73,76,79-85,97-101, and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,578,009 to Kraus et al. in view of US Patent No. 5,613,946 to McKeever.

Kraus discloses a balloon structure shaft that removably receives a guide wire through an axial groove (37) in the shaft, as shown in Figures 5-9. The shaft (54 or 71) has a passage (61 or 74) for removably receiving the guide wire (55 or 75). The shaft passage (61,74) has an axial groove (37) for removal of the elongate member (55 or 75) (see esp. Figure 5). Figures 1-2 show the balloon structure in more detail. A balloon sleeve (25) is disposed over a shaft (13) and has a passage that is slidable over a guide wire (11).

Kraus only discloses the elongate member as being a guide wire, instead of a catheter with a guide wire lumen as required by the claims. McKeever discloses a similar device in Figures 4-7 that includes a balloon catheter removably attached to another catheter. McKeever teaches that removably attaching another catheter body to a balloon catheter shaft allows for multiple tasks to be performed simultaneously (columns 1-2). Similar to Kraus, the balloon shaft communicates with a balloon while another lumen receives the second catheter body (column 1, line 67 through column 2, line 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the Kraus device to removable receive a catheter body with a guide wire lumen in place of the guide wire, as taught by McKeever, as this would provide the user with the capability of performing multiple tasks simultaneously. Further, it would have been obvious to one of ordinary skill in the art to form the axial groove of the modified Krause device so that the transverse edges of the groove are spaced from one another, as shown in Figure 7 of McKeever.

Regarding claim 23: see lines 30-40 of column 3 in Kraus.

Regarding the dimensions limitations: Kraus discloses some dimensions for the various components in column 6, line 55 through column 7. The shaft with the groove can have a length of 25 cm. Kraus states that typical catheter length is about 135 cm (column 1, line 33). The balloon length is about 3-6 cm. McKeever teaches that the diameter of a catheter is about 6-8 French (column 3, line 61) and the diameter of a guide wire lumen is about 0.035 inch (column 3, line 66). It is well known in the art for catheter bodies to taper at the distal end and have atraumatic tips. Kraus teaches that it is obvious to modify the dimensions of the device (column 6, lines 57-68).

Kraus also teaches that any materials known in the art can be used for construction of the device, including polymers and metal alloys, including nickel-titanium alloy (column 7, lines 1-10).

Regarding claims 21 and 71: It would have been obvious to one of ordinary skill in the art to form the catheter body from multiple connected members, as it has been held that constructing a formerly integral structure in various parts involves only routine skill in the art.

6. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus et al. in view of McKeever, as applied to claims 1 and 2 above, and further in view of US Patent No. 5,395,335 to Jang.

The modified Kraus device fails to form the axial groove as multiple intermittent grooves, but Jang teaches that an axial groove in a catheter can be perforated as an alternative to a continuous groove (column 9, lines 35-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the axial groove of the modified Kraus device in a perforated configuration, as Jang

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teaches that is simply a functionally equivalent way to form an axial groove in a catheter for removal of an elongate body from a lumen.

Response to Arguments

7. Applicant's arguments, see pages 10 and 11, filed 1/25/06, with respect to the 103 rejection(s) under Daniels et al. and Kramer have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kraus et al. and McKeever.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. Re. 35,104 (Solar) and US Patent No. 4,762,129 (Bonzel) disclose balloon structures with passages for elongate bodies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW

3/15/06

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Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER